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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,168	12/20/2007	Yasuomi Takagi	10084-0003.00000	2298

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EXAMINER

BOWMAN, AMY HUDSON

ART UNIT	PAPER NUMBER
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1635

NOTIFICATION DATE	DELIVERY MODE
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05/04/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/567,168	Applicant(s) TAKAGI ET AL.	
	Examiner AMY BOWMAN	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 February 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 11-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/3/06, 12/20/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's election with traverse of group I, claims 1-10, in the reply filed on 2/11/10 is acknowledged. The traversal is on the ground(s) that each of the groups relate to a single inventive concept by being drawn to category 3 of 37 CFR 1.475(b). This is not found persuasive because category 3 is directed to a product, a process specially adapted for the manufacture of the said product, and a use of the said product; wherein the instant claims are directed to methods of making a dumbbell shaped DNA, methods of making a vector composition, a composition comprising primers, and a composition comprising the dumbbell DNA. Therefore, the claims are directed to categories with different search considerations, rather than a single product and method of making and using such. Furthermore, as defined by 37 CFR 1.475(b), the product must be the first claimed invention in order to have unity of invention with a process/process(s).

The requirement is still deemed proper and is therefore made FINAL.

Claims 11-32 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 2/11/10.

Sequence Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1)

Art Unit: 1635

and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because there are sequences in the specification (pages 9, 10, and 21), as well as in the claims (claims 22 and 23) that do not contain a SEQ ID NO.

A complete response to this office action must correct the defects cited above regarding compliance with the sequence rules and a response to the action on the merits which follows.

The aforementioned instances of failure to comply are not intended as an exhaustive list of all such potential failures to comply in the instant application. Applicants are encouraged to thoroughly review the application to ensure that the entire application is in full compliance with all sequence rules. This requirement will not be held in abeyance.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schakowski et al. (Molecular Therapy, Vol. 3, No. 5, May 2001, pages 793-800), in view of Taki et al. (Nucleic Acids Research Supplement No. 3, 191-192, 2003), Scherr et al. (Cell Cycle, 2:3, 2003, pages 251-257).

It is noted that Schakowski et al. and Taki et al. are of record and cited on the IDS filed on 2/3/06.

Schakowski et al. teach synthesis of a vector that is small, linear, covalently closed, and dumbbell shaped. Schakowski et al. teach production of a DNA having a chain loop structure that is connected on both ends of two primers containing a target DNA to constitute a dumbbell DNA. Schakowski et al. teach a method of making the dumbbell via cutting of a two-chain DNA from a plasmid by a control enzyme, wherein one chain has a stem loop to produce the dumbbell when the chains are combined.

Art Unit: 1635

Schakowski et al. teach that the vectors yield more effective results than corresponding plasmids.

Taki et al. teach a direct and efficient synthesis method for dumbbell-shaped linear DNA using PCR, wherein the DNA includes a transcription unit (promoter and gene of interest). The DNA is generated by amplification of a gene of interest with PCR and a primer pair, cleavage to yield two DNAs, and treatment with T4 DNA ligase.

Scherr et al. teach that siRNA molecules can be efficiently expressed as shRNA hairpins in the cell.

Methods of amplifying and producing dumbbell DNA molecules are known in the art that comprise amplifying a target DNA using primers, wherein the primers are capable of forming a loop sequence and have a part of the target sequence. The only difference between the instant method and the methods of the prior art is incorporation of a nickase recognition sequence, which is considered a matter of design choice given that nickase is a known enzyme and it is being used to perform the same function as enzymes of the prior art in the formation of dumbbells. Absent some unexpected property of incorporating a nickase recognition sequence, this element is considered a matter of design choice to result in a cleaved duplex.

It would have been obvious to produce a dumbbell shape DNA molecule via PCR methods of the art that produce a siRNA molecule in the cell, given that siRNA molecules are known to be efficiently delivered via hairpin molecules and dumbbell shaped molecules have known protective qualities for nucleic acid delivery.

Art Unit: 1635

There would be a reasonable expectation of success in expressing a siRNA from a dumbbell given that siRNA molecules are known to be efficiently cleaved from hairpin molecules once delivered to a target cell, wherein using a nickase recognition sequence is one manner of processing the dumbbell.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMY BOWMAN whose telephone number is (571)272-0755. The examiner can normally be reached on Monday-Thursday 6:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fereydoun G. Sajjadi can be reached on (571) 272-3311. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1635

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AMY BOWMAN
Primary Examiner
Art Unit 1635

/AMY BOWMAN/
Primary Examiner, Art Unit 1635